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Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DA C

**PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT
ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)**

Docket Number (Optional)

First named inventor: JAMES HARRAWAY

Application No.: 10/053,920

Art Unit: _____

Filed: _____

Examiner: Elenor Willis Brandy

Title:

Attention: Office of Petitions

Mail Stop Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:

- (1) Petition fee;
- (2) Reply and/or issue fee;
- (3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
- (4) Statement that the entire delay was unintentional

1. Petition Fee

☒ Small entity-fee \$ 810 (37 CFR 1.17(m)). Application claims small entity status. See 37 CFR 1.27.

☐ Other than small entity-fee \$ _____ (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of PTO-SB-64 (identify type of reply):

☒ has been filed previously on July 07 2003

☐ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of \$ _____

☒ has been paid previously on _____

☐ is enclosed herewith.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.137(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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3. Terminal disclaimer with disclaimer fee

- ☐ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.
- ☒ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of \$ 810 for a small entity or \$ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

James D. Harraway
Signature

01/06/11

Date

James D. Harraway

Type or Printed name

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Address

Lancaster Ca. 93535

Address

Registration Number, If applicable

661-317-2032

Telephone Number

Enclosures:

- ☒ Fee Payment
- ☐ Reply
- ☐ Terminal Disclaimer Form
- ☐ Additional sheets containing statements establishing unintentional delay
- ☐ Other: _____

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☐ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

☐ Transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

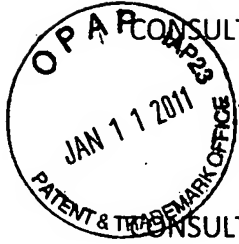
01/06/11

Date

James D. Harraway
Signature

James D. Harraway

Typed or printed name of person signing certificate



CONSULTATION REPORT

DATE OF CONSULTATION: 10/27/2003

CONSULTANT: Lingaiah Janumpally, MD

REQUESTED BY: Doddanna Krishna, MD, FCCP, FACP

REASON FOR CONSULTATION: Altered level of consciousness, aphasia, and right-sided weakness.

HISTORY OF PRESENT ILLNESS: The patient is a 49-year-old African American male with a history of morbid obesity and high risk factors, history of hypertension, hyperlipidemia, history of coronary artery disease, and history of cerebrovascular accident in 2002. The patient's coronary artery disease dates back to 2001. The patient underwent coronary angiography, noted to have severe three vessel coronary artery disease. Multiple stents were placed, and high coronary was occluded, and filling in the collaterals noted. He presented with chest pain and seen by Dr. Gill, Dr. Krishna, and Dr. Mahendra, with a diagnosis of acute chest pain, coronary artery disease, uncontrolled hypertension, history of cerebrovascular accident with some recovery.

The patient is currently admitted, seen by Dr. Tom Mahendra, underwent cardiac bypass surgery. Severe coronary artery occlusive disease, Coronary artery bypass x 2 using a single saphenous vein graft to the obtuse marginal artery and left internal mammary to the left anterior descending. The patient was on the vent, and the patient is extubated today, and the nurses had noticed that the right side was weak. The patient was answering the questions, yes, yeah, but he was unable to put the words together. He was also given morphine for the pain, and the patient was noted to have paralysis in the right arm and the right leg, and a neurology consultation was requested.

MEDICATIONS: The medications are reviewed. The patient is in simvastatin, furosemide, captopril, carvedilol (that is Coreg), aspirin, Tylenol, morphine, Levofloxacin.

The patient underwent bypass surgery yesterday, and today is 10/27/2003. The patient is extubated today.

PHYSICAL EXAMINATION: GENERAL: The examination shows the patient is off the vent, extubated. HEAD, EYES, and EARS, NOSE AND THROAT: The pupils do react to the light. The face looks asymmetric with a right facial droop. The tongue is the midline.

Antelope Valley Hospital
A facility of the Antelope
Valley Healthcare District

PATIENT: HARRAWAY, James D
MRN: 00683809 ACCT#: 122537855
ATTENDING: KRISHNA, DODDANNA page 1



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Lancaster, CA 93534

CONSULTATION REPORT

Page 2

LOC/RM/BED: CCU 201 01 PT TYPE: I

ADM-DIS: 10/24/2003



QUESTIONS ANSWERED 12/20/10

The Function of a Hemodialysis Machine:

The function of a hemodialysis machine would be based upon the process of dialysis filtering waste products out of the body. Dialysis actually begins when two solutions are separated by a membrane.

What is a solution?

The solution is a liquid containing a dissolved substance: the membrane is usually a very thin layer of tissue in a hemodialysis machine. The membrane used is a type of cellophane. To fully understand dialysis, the health care professional should understand the three processes that occur during the operations of a hemodialysis machine: diffusion, osmosis, and ultra filtration.

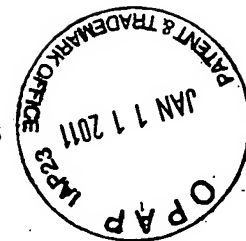
Diffusion: is the movement of particles from a solution with a high concentration to a solution of lower concentration. Concentration is referred to the number of particles dissolved in it, than does a solution of lower concentration. For example: if the health care professional dissolves two spoonfuls of salt in a glass of water, that solution would be a higher concentration than a solution containing only one spoonful of salt.

Osmosis: refers to the movement of liquid through a membrane from a solution of lower concentration to one of higher concentration. Osmosis and diffusion occur simultaneously.

To further illustrate the processes of diffusion and osmosis. Consider the following example, it the health care professional fill a cellophane bag with a salt solution (salt dissolved in water) seals it, and puts the bag in a container of pure water, the pure water will become salty and the solution in the sealed cellophane bag would be less salty. This happens because the cellophane has millions of tiny holes, or pores. The particles of salt are small enough to pass or diffuse, through the pores and into the pure water particles can pass back, and forth between the two solutions; however more particles will pass from the solution of higher concentration to the lower concentration. This is the process of diffusion. While the particles in the solution tend to pass from areas of high concentration to areas of lower concentration, then it will pass in the opposite direction-that is from the solution of lower concentration to the solution of higher concentration. Thus in solution containing less salt, There is more water in summary. Water will tend to move in opposite direction from that in which the particles tend to move. This is the process of osmosis.

Ultra filtration: involves removing fluid from a solution. If the solution on one side of the membrane is under greater pressure than the solution on the one side of the membrane is under greater pressure than the solution on the other side, the extra pressure will tend to force the fluids through the membrane toward the solution under lower pressure. Ultra filtration also occurs simultaneously with diffusion and osmosis.

The EKG part of machine: The EKG part of the machine can and will track the patient heart rate, while the patient is on the dialysis machine. The most commonly used electrode placement is known as the three standard-limb leads, Einthoven triangle. So then the heart is excited from 50 to 90 beats per minute in the average patient today. This heart rate will increase rapidly to 150 beats per minute. The machine will alarm and then the signal will tell the healthcare professional the patient is in trouble. We have developed a micro processing technology that accurately generates a real time graph in the dialysis machine. Out puts can be provided on graph paper or on the screen. It will be a continuing update on the heart based on the Arrhythmia. If a patient is experiencing an irregular and potentially dangerous heart pattern the system also can sound an alert. The nursing staff, in dialysis will intervene and prescribe medication so that their heart will return to the normal pattern of heart rate.



Lab type: The machine function will show arterial red blood cells count, this is real time display. So blood can be given if a patient is clotting. Co2 /pulse oz, it will monitor the oxygen and blood.

In order to better understand the function of the Absolute machine, I have illustrated the functions that will take place with the new innovative Absolute machine. And I will like the patent to show safety enhancements that it will be mobile, and user friendly. It will be cost effective, and it will set a cool trend for users today. Multifaceted and color ordered by patients.



SCHEDULE I

United States Patent Application
Kind Code
Harraway, James

20030136725
A1
July 24, 2003

Portable dialysis machine

Abstract

The portable dialysis machine may include an enclosure having a removable base. There may be a front panel having associated therewith multiple external connectors, smart function keys, a touch panel element and a voice-activated sensor. The front panel may be in communication with an electronic circuit element having a controller in communication therewith. There may be a blood flow element and a hydraulic flow element. A water reservoir and power supply may be included. It is emphasized that this abstract is provided to comply with the rules requiring an abstract that will allow a searcher or other reader to quickly ascertain the subject matter of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

Serial No.: Series Code: Filed:

Inventors:
Correspondence
Name and
BEECH
Address:

Harraway, James; (Palmdale, CA)
Dennis W. Beech
LAW OFFICES OF DENNIS W.

Serial No.
Series Code
Filed

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053920
10
January 24, 2002

U.S. Current Class:
U.S. Class at Publication:
International Class:

210/321.71
210/321.71
BOID 061/28



Claims

I claim:

1. A dialysis machine for performing kidney dialysis comprising: an enclosure having a removable base; a front panel having associated a plurality of connectors, a plurality of smart function keys, a touch panel element and a voice activated sensor; said front panel in communication with an electronic circuit element having a controller in communication therewith; a blood flow element including a hydraulic flow element; and a water reservoir and a power supply.
2. The dialysis machine as in claim 1 wherein said electronic board element further comprising: a processor module in communication with a data acquisition module; and said data acquisition module in communication with an interface module.
3. The dialysis machine as in claim 1 wherein said electronic board element further comprising a video module in communication with said touch panel element, a laboratory display, an ECG display and a pulse display.
4. The dialysis machine as in claim 1 wherein said plurality of connectors comprise a blood pressure device input, an ECG device input and a pulse device input.
5. The dialysis machine as in claim 1 wherein said blood flow element comprising: a blood pump and a dialyzer; an arterial chamber having a transducer and a venous chamber having a venous transducer; a port; and said blood flow element in communication with said electronic board element and connectable to a patient blood flow system.
6. A dialysis machine for performing kidney dialysis comprising: a blood flow element in communication with an electronic circuit element and a touch panel element; and said blood flow element comprising: a serial blood flow path; a blood pump and a dialyzer; an arterial chamber having a transducer and a venous chamber having a venous transducer; and a port and said blood flow element connectable to a patient blood flow system.



Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to kidney dialysis machines and more particularly to portable dialysis machines. The new dialysis machine includes additional sensor and monitor functions related to blood parameters and general client status during the dialysis process.

[0002] Various systems are used to accomplish the kidney dialysis operation and a variety of equipment configurations are currently known in the art. There are fairly simple portable dialysis machines as well as loosely integrated complex systems used in chronic care environments. Historically dialysis machines have operated with fixed operating parameter functions allowing little operator interaction. This was partially due to safety considerations, less need for operator training, and consistent, repeatable treatment of patients.

[0003] More recently it has been thought that more operator interaction for a particular patient may provide better treatment results. With the advent of the use of computers or smart controllers to aid the operator and to monitor safety concerns, it has become possible for more flexible, self-contained operator controlled dialysis machines. This is particularly true for portable dialysis machines that receive the benefit of the miniaturization of elements for use in such machines.

[0004] An example of a portable system which discloses a significant amount of operator control is disclosed in U.S. Pat. No. 5,609,770. This invention includes a dialysis machine mounted on wheels and having a touch panel display for operator interaction. The dialysis machine has one or more micro controllers to operate and control the hydraulic and blood flow paths. Also included is a safety or protective micro controller to monitor safety both in terms of operator actions and in equipment operation.

[0005] The system interface involves a touch screen display that includes display of images equivalent to labeled push button switches for the operator to select functions and set parameter values of the system. The dialysis machine includes many of the traditional monitor parameters and controls for dialysis machines that were preset and not available for direct operator control. However, the disclosure does not include or anticipate blood sampling and laboratory type analysis, pulse monitoring or electrocardiogram monitoring in dialysis machines. Also, use of voice activation technology by a patient in an emergency situation is not a functional element.

[0006] While systems for analysis of the hydraulic flow path have been disclosed as for example in U.S. Pat. Nos. 5,024,756 and 5,744,027, the evaluation of the blood parameters in the blood flow path to detect blood clotting, hemoglobin clotting time and triponet has not been implemented in currently known machines. Any such analysis is done separate *from* the dialysis unit. Performing blood tests such as blood clotting may



improve the affectivity of the dialysis process in patient treatment.

[0007] The present invention may sample and test the blood of the patient during dialysis for evaluating dialysis affectivity and for input to adjust operational parameters. Monitoring of the patient pulse and ECG data to monitor patient wellbeing during the dialysis process may be performed. There may be improved safety of use of dialysis machines in situations wherein the patient is not continuously monitored by a human operator.

[0008] As can be seen, there is a need for an integrated, portable dialysis machine that includes blood analysis, pulse monitoring and ECG monitoring.

SUMMARY OF THE INVENTION

[0009] The present invention dialysis machine may include an enclosure having a removable base. There may be a front panel having associated therewith multiple external connectors, smart function keys, a touch panel element and a voice activated sensor. The front panel may be in communication with an electronic circuit element having a controller in communication therewith. There may be a blood flow element and a hydraulic flow element. A water reservoir and power supply may be included.

[0010] These and other features, aspects and advantages of the present invention will become better understood with reference to the following drawings, description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 illustrates a front elevation view according to an embodiment of the invention;

[0012] FIG. 2 illustrates a side elevation view thereof;
<http://appftl.uspto.gov/neta/gilnph->

[0013] FIG. 3 illustrates a functional schematic diagram of the blood flow path of the dialysis machine according to an embodiment of the invention;

[0014] FIG. 4 is a schematic diagram of elements of an electronic board element according to an embodiment of the invention;

[0015] FIG. 5 is a schematic diagram of a video module interface according to an embodiment of the invention.



DESCRIPTION OF THE PREFERRED EMBODIMENT

[0016] The following detailed description is the best currently contemplated modes for carrying out the invention. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention.

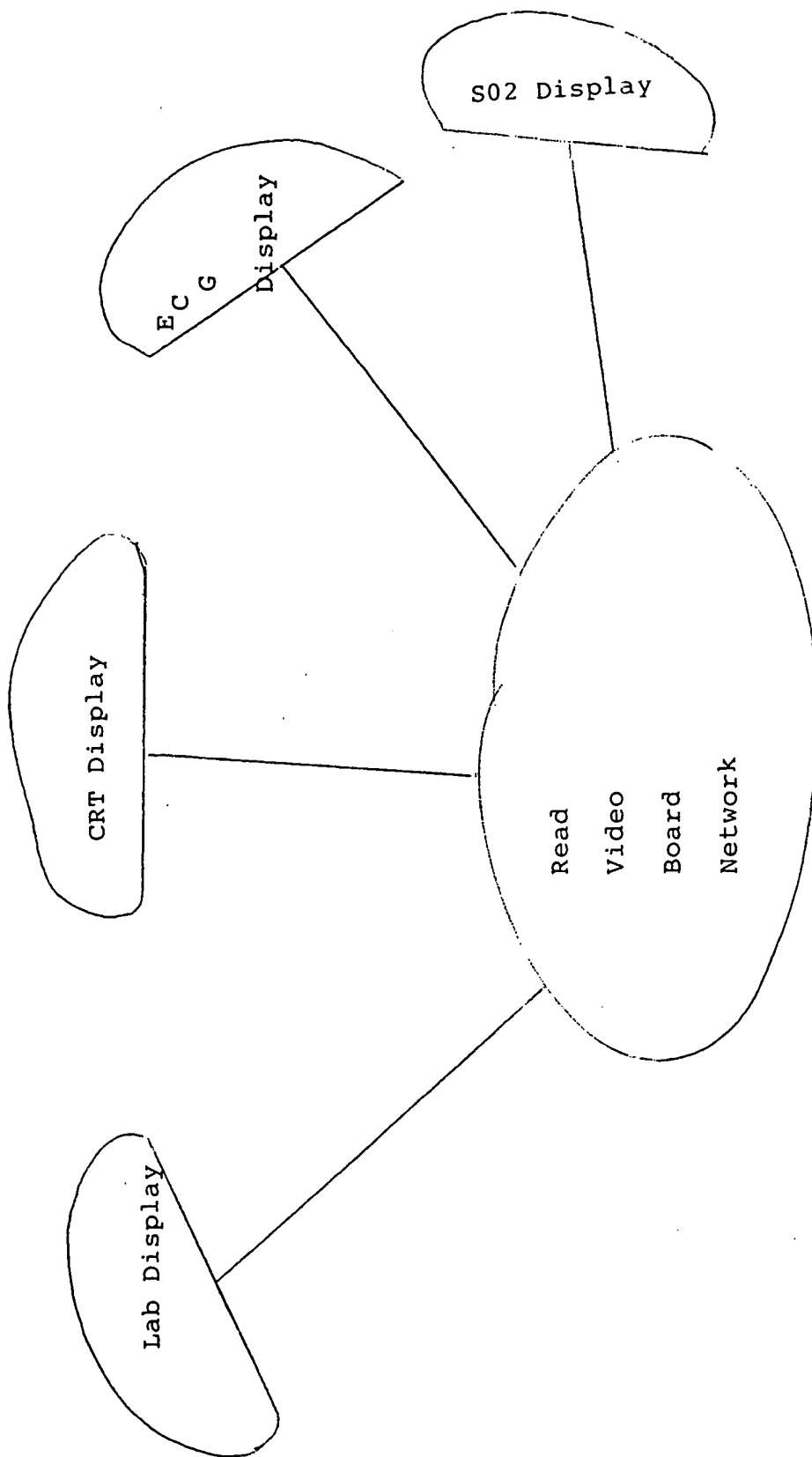
[0017] Referring to FIG. 1, a dialysis machine 10 has a touch panel control element 20 for display and control in cooperation with a controller (not shown). The controller may be programmed with patient information and to display the traditional parameters used in dialysis that may then be set to required values for a particular patient to be treated. Also, parameters to be continuously monitored such as patient treatment as well as alarm parameters may be displayed and controlled. The portable dialysis machine 10 is mounted on a removable base 11.

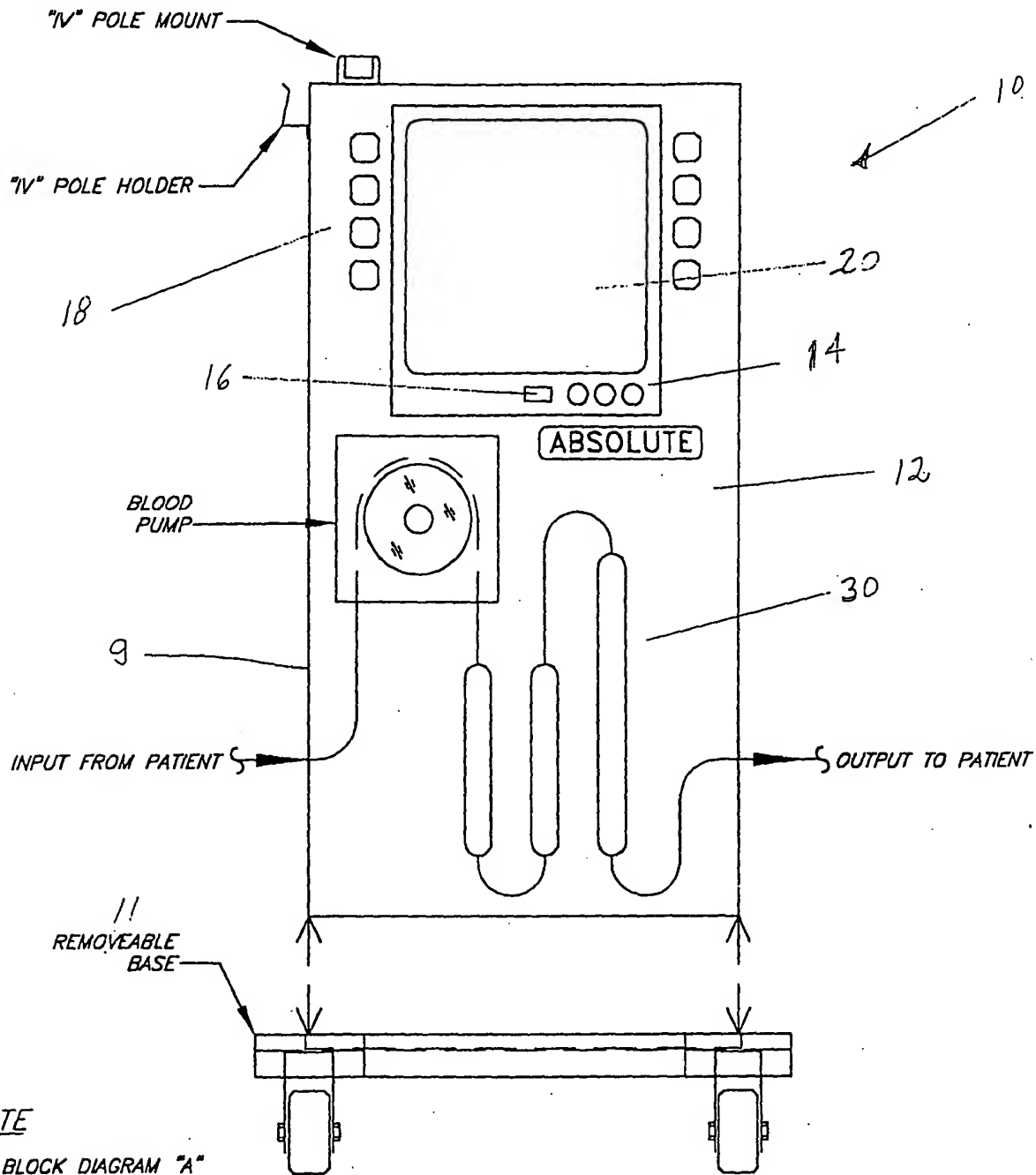
[0018] There may be provision for smart function keys 18 for use in communication between Ethernet and the data acquisition board, central paging of a doctor and e-mail to the touch panel element 20. There may be also front panel connectors 14 for blood pressure, pulse and ECG input devices. Also a printer connector 16 may be included on the front panel 12 of the dialysis machine 10. There is front panel 12 access to the blood flow element 30 of the dialysis machine 10.

[0019] Referring to FIG. 2, the general arrangement of elements is illustrated. The touch panel element 20, electronic board module 22 that includes the controller 23 and the power supply 28 may generally be located in the front portion of the enclosure 9. Space is also allocated behind the front panel 12 for the blood flow element 30. The hydraulic flow element 50 is located behind the blood flow element 30. A water reservoir 52 may be located in the rear of the enclosure 9.

[0020] The electronic board element 22 may be further partitioned into an interface module 24, a data acquisition module 25, a processor module 26 and a video module 27 as illustrated in FIGS. 4 and 5. The processor module 26 may control the data acquisition module 25 communication with an external Ethernet, central paging system, e-mail system and the interface module 24. The interface module may in turn communicate with external analog equipment. The video module 27 may control the touch panel element 20 as well as an external laboratory display 82, ECG display 84 and pulse display 86. The power supply 28 may be connected to a dialysis pump, valves, balancing chamber, heparin pump, laboratory segment, heater, hydraulics, and conductor and temperature probes.

[0021] Referring to FIGS. 2 and 3, a port 34 may be included in the blood flow path 32 to sample blood for laboratory analysis. A blood analysis device 36 may be incorporated in the enclosure 9 and the results of a blood analysis communicated to the controller 23. The blood sample may also be sent separately to a laboratory for analysis. Particular blood analysis parameters to be checked during dialysis include blood clotting, hemoglobin clotting time and triponet for evaluation of blood count, blood clotting time and patient heart distress such as a heart attack.





NOTE

* SEE BLOCK DIAGRAM "A" FOR DETAIL

FIG. 1

H & H MEDICAL REPAIR LLC

PRELIMINARY CONCEPT DRAWING
"ABSOLUTE" DIALYSIS MACHINE PROJECT

DATE: 07/21/01

DESIGNER: JAMES HARRAWAY

DRAFTSMAN: STEVE CLAYTON

DRAWING NAME: ABSOLUTE_1

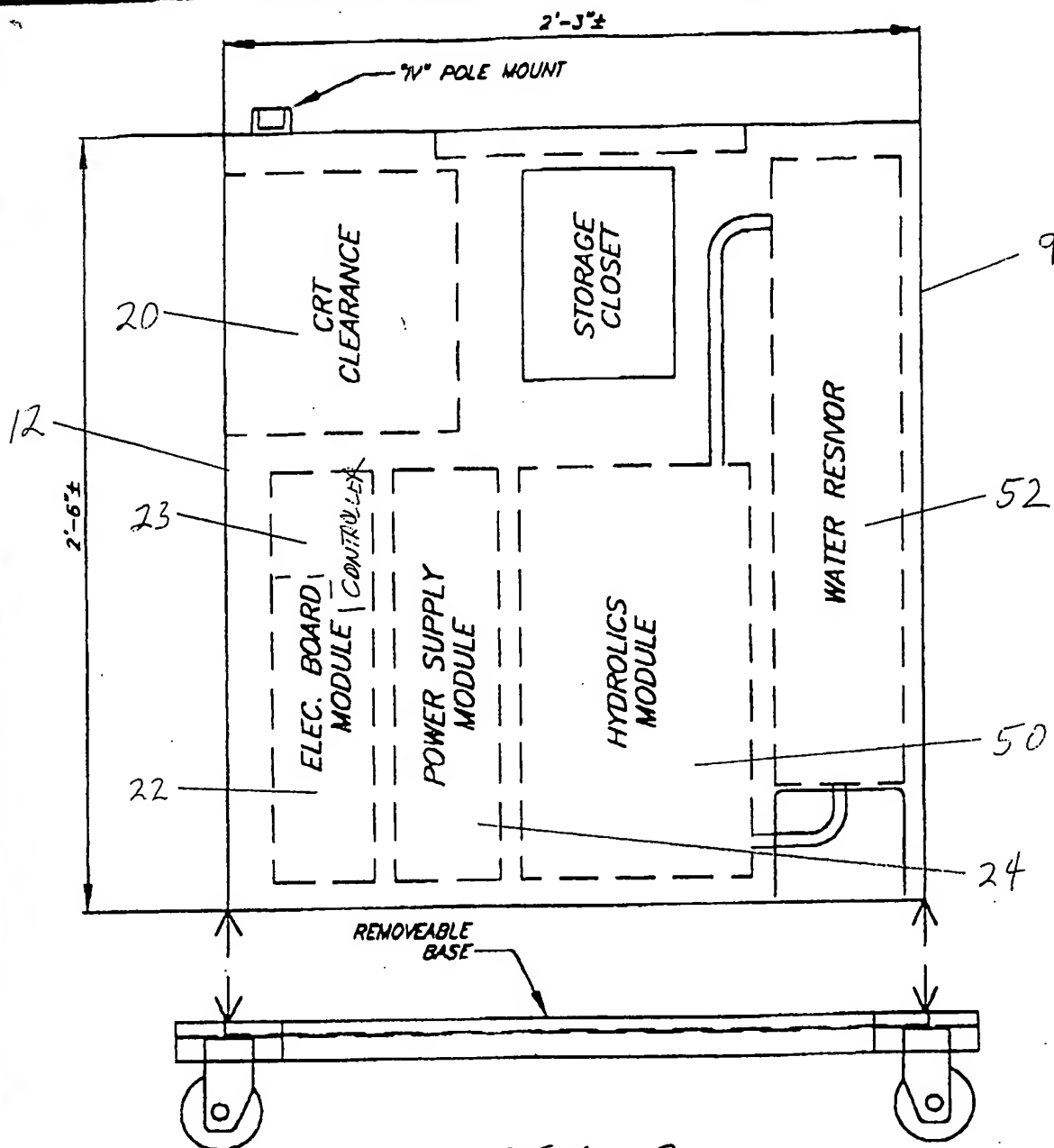


FIG. 2

H & H MEDICAL REPAIR LLC

PRELIMINARY CONCEPT DRAWING
"ABSOLUTE" DIALYSIS MACHINE PROJECT
SPACE USAGE

DATE: 07/21/01

DESIGNER: JAMES HARRAWAY

DRAFTSMAN: STEVE CLAYTON

DRAWING NAME: ABSOLUTE_1

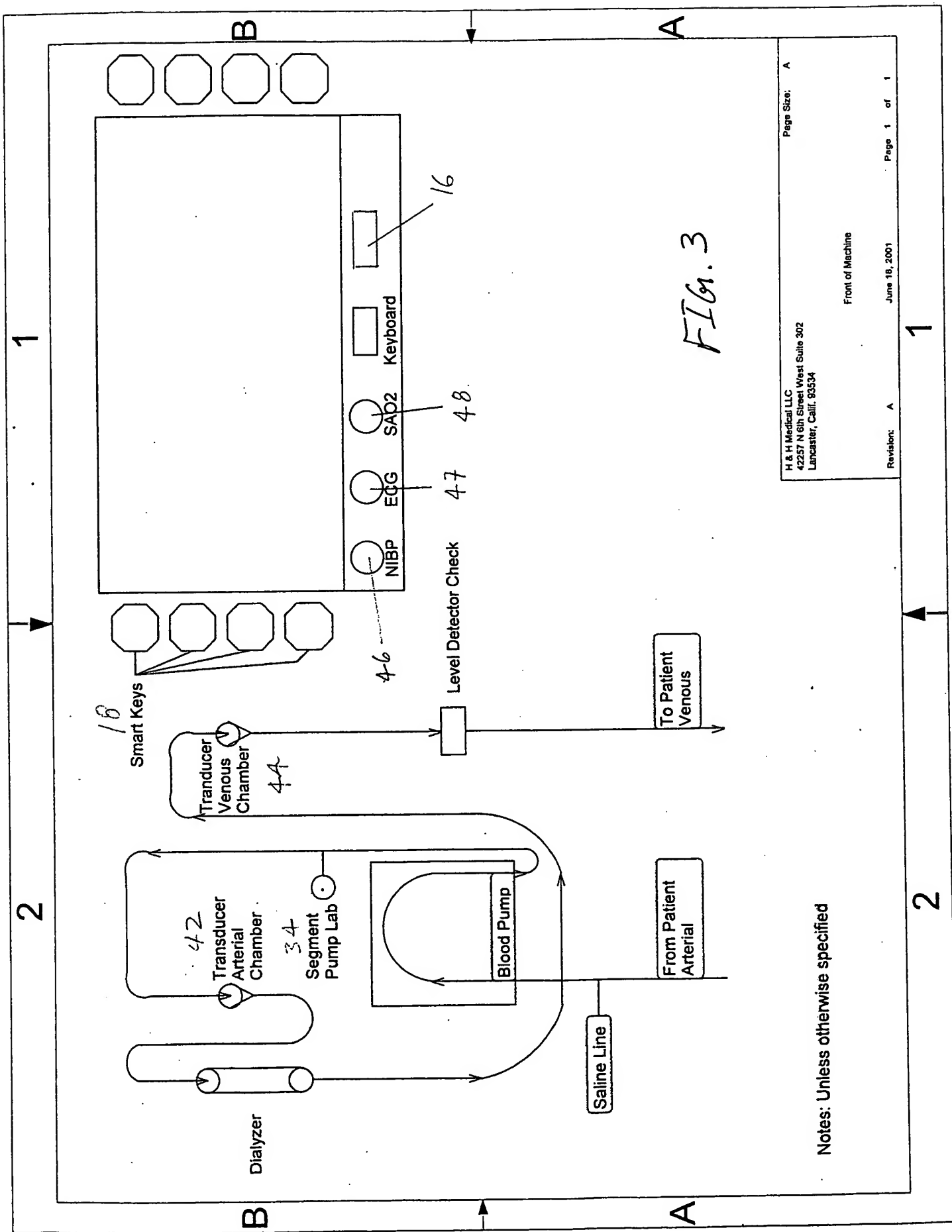


Fig. 3

Notes: Unless otherwise specified



H&H MEDICAL REPAIR LLC.

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LANCASTER, CALIFORNIA 93534

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JAMES HARRAWAY

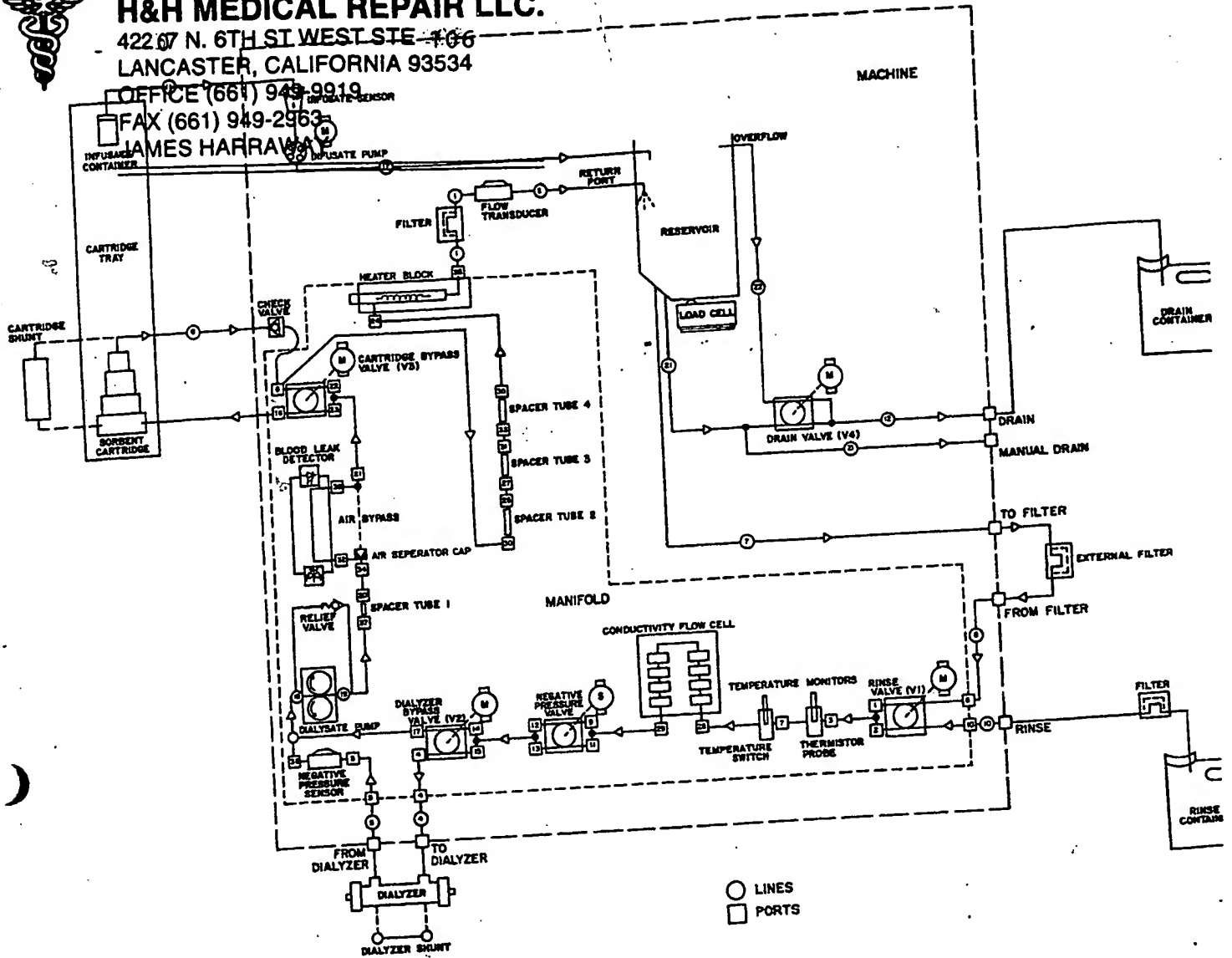
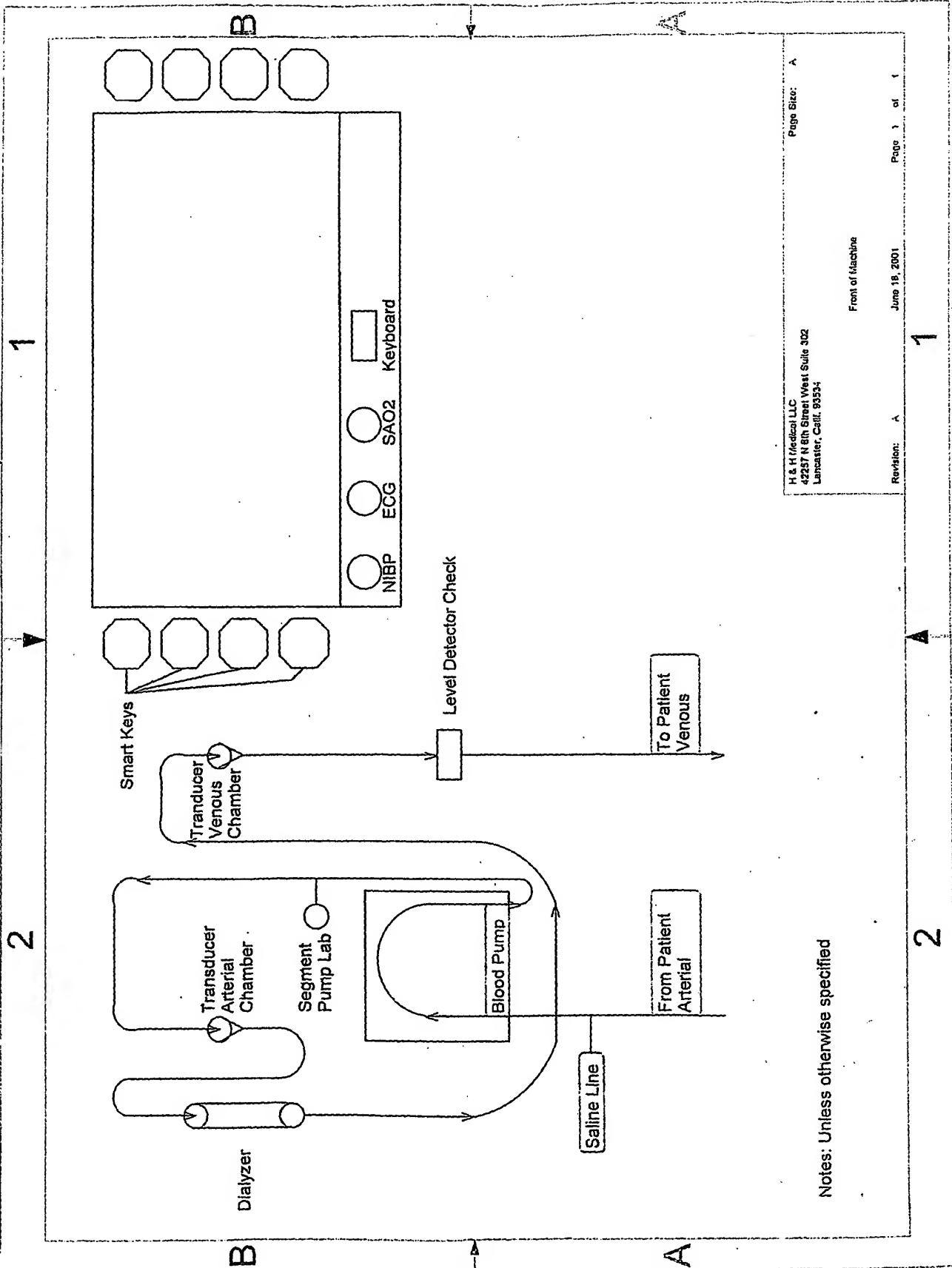


Figure 4.1: Hydraulic Schematic Diagram



H & H Medical LLC
 42257 N 5th Street West Suite 302
 Lancaster, Calif. 93534

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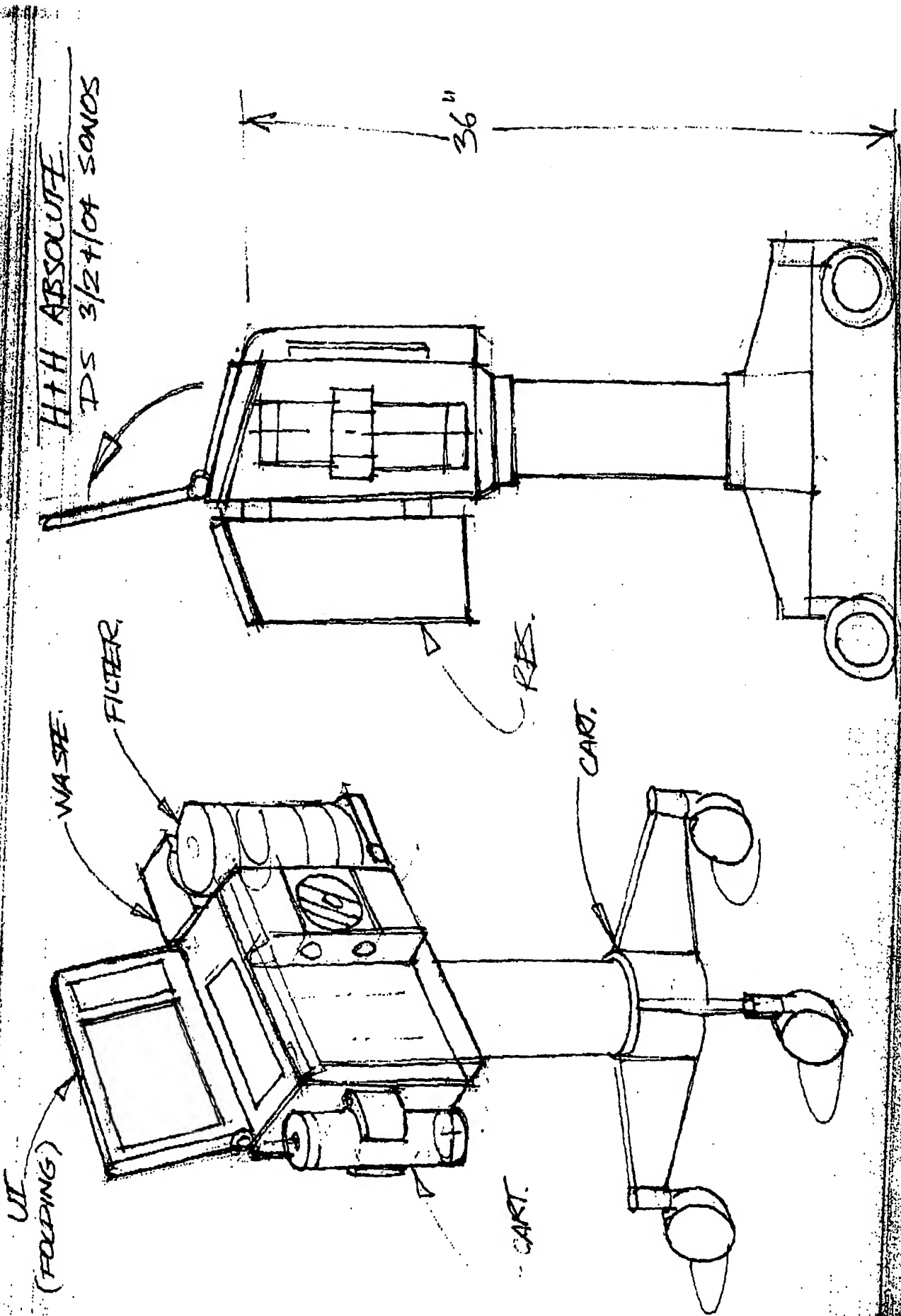
Front of Machine

Revision: A

June 18, 2001

Page 1 of 1

Notes: Unless otherwise specified



Here are ANSWERS
to Office Action.

Jan 6, 2011 James Harraway

